

The Body Hunters: As Drug Testing Spreads, Profits and Lives Hang in Balance

By Joe Stephens
Washington Post Staff Writer
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First of six articles

KANO, Nigeria – By the time word of the little girl's death reached the United States, her name had been replaced by numerals: No. 6587-0069.

She was 10 years old and a scant 41 pounds. She lived in Nigeria, and in April 1996 she ached from meningitis.

An epidemic raged and scores lay dying in this frenetic city of amber dust. Somehow the girl found a refuge: a medical camp where foreign doctors had arrived to dispense expensive medicines for free.

Behind a gate besieged by suffering crowds stood two very different clinics. A humanitarian charity, Doctors Without Borders, had erected a treatment center solely in an effort to save lives. Researchers for Pfizer Inc., a huge American drug company, had set up a second center. They were using Nigeria's meningitis epidemic to conduct experiments on children with what Pfizer believed was a promising new antibiotic – a drug not yet approved in the United States.

The experimental drug was a potential blockbuster: Wall Street analysts said Pfizer might reap \$1 billion a year if Trovan, as it was known, won approval for all its potential uses. Pfizer also wanted to test the drug for use against meningitis, including an epidemic strain. The company couldn't find enough patients in the United States, so its researchers had come to Kano, among the dying.

Doctors working with Pfizer drew spinal fluid from the girl, gauged her symptoms and logged her as patient No. 0069 at testing site No. 6587 in experiment No. 154-149. They gave her 56 milligrams of Trovan.

A day later, the girl's strength was evaporating, Pfizer records show, and one of her eyes froze in place.

On the third day, she died.

Pfizer records are explicit. Action taken: "Dose continued unchanged." Outcome: "Death."

Nobody can know for certain if the girl would have lived had she been taken off experimental Trovan; perhaps she was beyond all hope. Yet the circumstances of her death – while taking an unapproved drug, with alternate treatments at hand, in a hurriedly established private sector experiment – suggest much larger problems.

A Washington Post investigation into corporate drug experiments in Africa, Asia, Eastern Europe and Latin America reveals a booming, poorly regulated testing system that is dominated by private interests and that far too often betrays its promises to patients and consumers.

Experiments involving risky drugs proceed with little independent oversight. Impoverished, poorly educated patients are sometimes tested without understanding that they are guinea pigs. And pledges of quality medical care sometimes prove fatally hollow, The Post found.

Drugmakers hop borders with scant government review. Largely uninspected by the Food and Drug Administration – which has limited authority and few resources to police experiments overseas – U.S.-based drug companies are paying doctors to test thousands of human subjects in the Third World and Eastern Europe.

The companies use the tests to produce new products and new revenue streams, but they are also responding to pressure from regulators, Congress and lobbyists for disease victims to develop new medicines quickly. By providing huge pools of human subjects, foreign trials help speed new drugs to the marketplace – where they will be sold mainly to patients in wealthy countries.

The FDA requires that patients in such tests, no matter where they live, consent fully to the experiments if the results are to be used to win marketing approval in the United States. And, in fact, many tests conducted in the Third World are conducted carefully and serve to expedite the creation of life-saving drugs. But the Post's investigation found that in other instances, the rules are poorly enforced or ignored.

The experiments raise questions about corporate ethics and profits on a frontier of globalization where drug companies wield enormous influence, and where doctors paid by U.S.-based corporations sometimes perform experiments on ill-informed patients in authoritarian societies.

A Nigerian physician who said he was present during the Kano experiment, for instance, felt it was "a bad thing," but he did not object because Pfizer's test appeared to have backing from the government. "I could not protest," said the physician, Amir Imam Yola. "The system you have in America and the system we have here, there is a wide gap. Freedom of speech is still not here."

At the time, Nigeria was run by a military government that had one of the world's worst human rights and corruption records.

Industry guidelines for conducting meningitis experiments never envisioned testing an antibiotic amid a terrible epidemic in a squalid, short-staffed medical camp lacking basic diagnostic equipment.

Texas pediatrician George McCracken, a leading meningitis specialist who co-authored the guidelines, said he was surprised Pfizer's researchers had attempted such a venture. "I just wouldn't do a study that way myself," he said. "I know they wanted to get the data. They wanted to go fast. They wanted to move ahead. I'm not sure they made a smart decision."

Among the 200 stricken children enrolled in its experiment, 11 died and others suffered meningitis-related symptoms such as deafness, lameness, blindness, seizures, disorientation and, in one case, an inability to walk or talk, company records show.

Pfizer said its goal was to study the safety and effectiveness of its antibiotic while simultaneously pioneering a breakthrough treatment for the Third World. The company contends its practices were validated – especially given the horrendous conditions it found – by the number of children who showed improvement and a fatality rate of about 6 percent, which compares favorably to those reported for bacterial meningitis victims treated at U.S. hospitals. The Trovan experiment, a company spokeswoman said, was approved by a Nigerian ethics board and "was sound from medical, scientific, regulatory and ethical standpoints."

Pfizer researchers prepared the study over six weeks, instead of the year or longer common in the United States. And while American meningitis patients generally receive fast-acting intravenous medicines, the researchers gave most of the Nigerian subjects an oral form of Trovan that the company said had never been tested in children.

Ten doctors interviewed about Patient 0069's death – including pediatricians, meningitis specialists and physicians who have practiced in developing countries – said they were troubled by her case. Their questions focused in part on whether doctors left the child on the test drug for too long while her health declined. Generally, if human subjects are not responding to an experimental treatment, they are removed from the test and given proven medicines.

Industry guidelines governing meningitis experiments urge that researchers conduct a second spinal tap a day or so after treatment begins to see if the medication is working. Pfizer researchers chose to make such exams optional in Nigeria and Pfizer said they did not perform one on Patient 0069, leaving her on the experimental drug until her death.

"It could be considered murder," said Evariste Lodi, the Doctors Without Borders physician who led the charity's efforts against meningitis in Kano, after he reviewed a Pfizer description of Patient 0069's death. Added Agwu Urondu, a Nigerian physician still working in the city: "The patient died because [the doctor] refused to help."

In a written statement, a Pfizer spokeswoman said a death such as Patient 0069's could occur during treatment with any antibiotic and that researchers had no reason to suspect the experimental medicine was not working.

Abdulhamid Isa Dutse, a Nigerian doctor hired by Pfizer to run the experiment, agreed that physicians should alter the medication of a patient who is not improving. "To be very, very honest, in retrospect, maybe we should have done something about that," he said of the girl.

Yola, the Kano doctor, and others who battled the epidemic said patients did not understand they had been in an experiment. "The patients did not know if it was research or not," agreed a Nigerian laboratory technician who took part. "They just knew they were sick."

Pfizer disputes that, saying local nurses explained the research to families, even though the company has no signed consent forms to prove it.

Although Pfizer eventually won approval to sell the drug to adults in the United States, in the end its push to bring Trovan to market turned out badly. Authorities never approved marketing the antibiotic for use by children in the United States or Nigeria. U.S. regulators discovered dozens of discrepancies in the Kano test results. Last year, they advised doctors to restrict Trovan's use in adults because patients had suffered liver damage and death. European regulators suspended sales altogether.

Pfizer's Nigerian clinic opened and closed in a relative eye blink: About three weeks after the company's team roared in with a chartered DC-9, the team roared out. Pfizer's doctors returned once to examine the patients but did not track their long-term recovery.

"If I had the power," said Doctors Without Borders physician Lodi, who watched the experiment unfold from across the compound, "I would take away their medical licenses."

A Desperate Time

Pfizer's path to Kano began on the Internet.

Pfizer physician Scott Hopkins was on the World Wide Web when he learned of a meningitis epidemic racing across northern Nigeria. The often-deadly infection of the brain and spinal cord had begun to kill hundreds upon hundreds in a region already staggering under epidemics of cholera and measles. Some victims lay prone on bare ground in convulsions, physicians recalled. By February 1996, 120 new patients were arriving at Kano's poorly equipped, feces-stained infectious disease hospital every day.

For Pfizer, the timing was oddly fortuitous. The New York-based, then-\$11 billion-a-year corporation was pushing to submit Trovan for FDA approval. A bacteria fighter, Trovan had shown promise against a broad range of infections – sinusitis, bronchitis, gonorrhea and pneumonia. Thousands of patients had enrolled in international drug studies in the company's biggest testing program ever. Wall Street analysts predicted that Trovan could be one of the most financially successful new drugs of its kind in years.

There were worries, however, about possible side effects in children. Trovan belonged to the quinolone class of antibiotics, and quinolones had caused joint damage in experiments on young rabbits and puppies.

Pfizer knew that the company needed extensive, convincing tests that proved Trovan was safe and effective in order to gain approval for the drug's use on children. But illnesses such as bacterial meningitis were relatively rare in the United States.

"We had to move quickly" after spotting the epidemic, explained Pfizer spokeswoman Betsy Raymond. "You would not be able to find those numbers of children with spinal meningitis in the U.S."

Hopkins, who then headed Trovan development, said he proposed leading a six-person team into the epidemic in an attempt to establish that Trovan in oral form could work as well in children as a fast-acting intravenous antibiotic. If successful, oral Trovan would mark a breakthrough in battling epidemics in the Third World. Children could simply swallow a pill once a day, eliminating risky injections.

Hopkins said he was confident of Trovan's potency and that he pitched the plan to senior Pfizer executives by arguing, in part, that a humanitarian thrust in Nigeria could create a "halo" over their newest product.

Pfizer said it authorized the venture solely to win FDA approval for Trovan use in meningitis epidemics, which occur mainly in developing nations. Hopkins says today that this designation proves that the experiment was philanthropic, not a cheap way to get the drug approved for American children.

But McCracken, who later conducted Trovan tests for the company, calls that argument "a little bit disingenuous. They do gain from it. They gained knowledge about how the drug works. It's not 100 percent altruistic." And under U.S. law, once the drug won FDA approval for any purpose, American pediatricians would be free to prescribe it.

One Pfizer child disease specialist, Juan Walterspiel, complained that the experiment was too risky – oral Trovan had never been tested on a child, he later alleged in a lawsuit. The suit ultimately was dismissed at the request of the physician and Pfizer; neither side would comment on the litigation for this article.

Hopkins, who has since left Pfizer, recalled in an interview that when he launched the experiment, he had data showing children had readily absorbed oral Trovan. Pfizer spokeswoman Kate Robins disagreed.

In fact, Robins said, only one child had taken the oral form of Trovan at the time. Pfizer has no knowledge of how that child fared, she said. But previous tests of the oral form on adults, and of an intravenous formulation of Trovan on children, showed it was well absorbed, she said.

Gary Overturf, a New Mexico child disease specialist, said that without oral studies in children, support for using oral Trovan on perilously ill Nigerian children would appear to have been "at best . . . thin." Another specialist, Creighton University pediatrics department Chairman Stephen Chartrand, said use of the oral drug under those circumstances would be "unconscionable."

Yet the experiment quickly won clearance in Nigeria after what company records call an "independent review" by authorities there and the approval of a Kano hospital ethics committee.

"That was kind of a desperate time for them – they were happy to have anyone come in and do just about any kind of work," Hopkins recalled of the Nigerian regime then in power.

Pfizer did not require FDA approval to conduct the trial, he said. The company gave regulators a copy of their plan anyway, he said, and the agency granted permission to export Trovan to Nigeria.

Within six weeks of his discovery of the meningitis outbreak, Hopkins recalled, Pfizer had chartered a DC-9 and he was jetting toward the epidemic's center.

Treatment and Tensions

The ancient walled city of Kano is an impoverished metropolis of 2 million people that sprawls across a scorched savanna. A choking white fog of pollution pumped by decrepit cars and speeding mopeds shrouds a labyrinth of buildings tacked together with corrugated metal and russet-baked earth.

Amid the clamor sits the Kano Infectious Disease Hospital, a compound of crumbling cinder-block bunkers. International aid workers call it one of the world's most fetid and overburdened hospitals. Rats chew on neglected corpses and patients defecate on the ground. Many wards lack water and electricity; walls are encrusted with excrement and blood.

Stunned, Pfizer's researchers reportedly confessed to locals they had expected a rural village, not urban chaos and squalor.

Doctors Without Borders, more accustomed to such conditions, had already begun improvements. The Nobel Peace Prize-winning charity, which races free care to public health disasters worldwide, had arrived weeks earlier with an inexpensive antibiotic called chloramphenicol. Its volunteers had organized patient screening and treatment, grouping the sick by the severity of their illnesses. The sickest patients slept inside in the compound's few battered beds and on benches; the less seriously ill occupied mats in tents.

Tension surfaced immediately – starting with control of the beds. Hospital officials gave the researchers two of the best-maintained patient wards, including much of the compound's coveted bed space, charity workers said.

"Very, very sick people were outside who could have had a bed inside," except that researchers wanted the beds for the experiment, complained Karin de Jonge, a Belgian nurse and the Kano field coordinator at the time for the charity.

Pfizer's test also drained away the most experienced Nigerian doctors and nurses, she said. The paycheck was tempting: One lab technician said the study, in effect, doubled her pay.

"That made us very angry," de Jonge said.

Hopkins called the Doctors Without Borders complaints "paranoid," saying the charity wanted sole credit for taming the epidemic. "I wouldn't give my dog" chloramphenicol, which he said had serious side effects. Hopkins also said that Pfizer upgraded conditions at the camp.

Pfizer said patient care was not "compromised" by the trial and that its physicians, support staff and equipment "substantially improved" the level of care.

But Lodi, of Doctors Without Borders, described Pfizer's disruptions as so serious that they alone may have contributed to patient deaths.

"In an epidemic, where you have a very high number of cases who will die, you don't go and experiment," added de Jonge. "You are talking about human beings, after all."

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The Body Hunters: Testing Amid an Epidemic

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The Experiment Begins

At first, the Pfizer researchers wanted only the most treatable children, not those near death. But once confronted with the tumult of the epidemic, any child who arrived at its wards was treated, Hopkins said.

Over two weeks, the Pfizer researchers assumed care of 198 children, most underweight and some only a few months old. The children were stricken with various stages of bacterial meningitis, which can escalate rapidly from fever to coma, convulsions, and death.

The experiment's plan called for half of the patients to get Trovan, either in a tablet, an oral solution or in an intravenous formulation that bypassed the digestive tract. The other half of the patients would receive an injection of the comparison antibiotic ceftriaxone, an effective meningitis treatment already approved for American children. Unlike the quinolones, ceftriaxone had never been associated with arthritis in lab animals.

Problems arose as soon as the experiment began. Children were supposed to have their blood tested on arrival and again after five days. But that plan was generally abandoned "due to the shortage of medical staff," according to an internal Pfizer report on the experiment.

Ceftriaxone was to be given by injection into a vein or muscle. But because of the shortage of skilled workers, the report said, the drug was almost always injected into the youngsters' buttocks or thighs to save time and trouble. The shots were severely painful, leading to "great fear and sometimes dangerous struggles with children," according to the report.

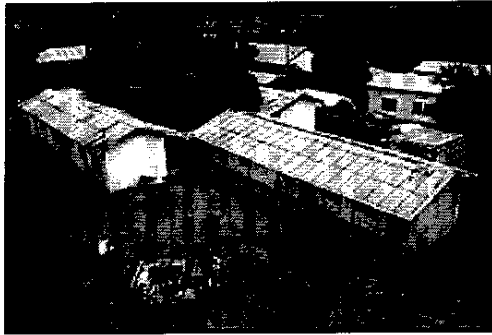
To reduce the pain after initial injections, the report said, researchers cut the volume of antibiotic given to children who were improving to one-third of the recommended amount. Pfizer said available data indicated the dose remained more than sufficient, but the drug's manufacturer, Hoffmann-La Roche, said the reductions could have sapped the drug's strength and skewed any comparison to Trovan.

"A high dose is essential," Hoffmann-La Roche medical director Mark Kunkel said, stressing that he had no independent knowledge of the experiment. "Clinical failures . . . and perhaps deaths of children could have resulted from the low dosing."

Deaths in Kano

Deaths were inevitable across the compound, regardless of who provided care. In January 1996, the death rate in the Kano region peaked at about 20 percent, according to Doctors Without Borders statistics. The rate plummeted as humanitarian groups airlifted in medicine, but by the end of the outbreak an estimated 15,800 Africans had perished.

In Pfizer's wards, the mortality rate was at least as low, if not lower, than in the charity's wards, Hopkins said. The questions that surfaced later focused on specific medical choices, especially the decision to use an unapproved oral antibiotic on very young, very ill children.



A man too sick to walk is carried into the Infectious Diseases Hospital in Kano, Nigeria. Michael Williamson "It would never be used like that in the United States," Hopkins said. "The standard is IV [intravenous] therapy."

Pfizer Vice President Paul S. Miller defended the decision in a written statement that he sent to a lawyer for Walterspiel, the former Pfizer doctor. The oral formulation was safe, Miller argued. Nonetheless, he said, the researchers had given critically ill Nigerian children antibiotic injections instead of the oral drugs. Doctors also could halt or modify treatment if the oral Trovan failed, he said.

Pfizer's internal report on the experiment showed children did die shortly after taking oral Trovan.

On April 6, 1996, a 7-year-old boy whose facial muscles had ceased functioning entered a Pfizer ward, the report said. Doctors labeled him patient No. 0054 and, despite his paralysis, gave the 39-pound boy 50 milligrams of oral Trovan.

Within nine hours, the report said, Patient 0054 was dead.

It also happened with Patient 0069, the 10-year-old girl. She grew worse over three days while taking no antibiotic except oral Trovan, confirmed Dutse, the Nigerian doctor who led the Pfizer test.

"Oh my God!" Urondu, the Kano physician, said after a reporter showed him Pfizer records recounting the girl's death. "It was an experimental drug for meningitis! You change – or even use two drugs, for God's sake!"

Marc Gastellu-Etchegorry, a Doctors Without Borders official who has helped evaluate drugs for use in developing countries, read the report at the charity's Paris headquarters and shook his head. "This is a mistake," he said. "When the patient is declining step-by-step, you try to give them a fighting chance. It can look like a murder if you don't."

McCracken, the meningitis specialist, said that when he helped Pfizer conduct a subsequent experiment with injectable Trovan in the United States, Africa and Latin America, he crafted written rules to protect failing patients.

"That wouldn't have happened in our study," McCracken said of Patient 0069's treatment. "Generally, if they don't improve over the first 48 hours, they are switched out."

Robins, the Pfizer spokeswoman, said in a written statement that things were different in the Nigerian epidemic,

where 48 hours was "too early to judge a response to therapy." The meningitis bacteria there had never proven resistant to quinolone antibiotics, she added, so no one was concerned the Trovan was not working. Robins also said that doctors gave the girl intravenous fluids after 48 hours, which she said satisfied industry guidelines that recommend changing a failing patient's "therapeutic regimen."

Pfizer also pointed out that the fatality rates in Nigeria were about equal among the patients who received oral Trovan, Trovan by injection and the comparison drug.

Hopkins stressed that no child would have been given the oral formulation unless he or she appeared well enough to swallow. Patient 0069 may have appeared relatively stable, he speculated, and then suddenly worsened on the third day, perhaps from complications set in motion before treatment began.

And yet, Dutse confirmed that he, like the physicians from the charity, considered it necessary to modify treatment of failing children. "You can't jeopardize a patient's life," he explained. Handed the report describing Patient 0069's death, Dutse confirmed he had written it, then stared at it silently. "I recollect this one," Dutse finally said. "She just died."

Dutse read the report again and then shrugged. "I don't know what happened. If a patient isn't doing well, you change the treatment. . . .

"Why we didn't do that, I don't know."

Missing Signatures

In the United States, researchers are required to carefully apprise patients of the risks of an experimental medicine. They describe its purpose and explain alternative treatments. Then the patient, their parents or an impartial witness must sign a written approval statement.

In Nigeria, the researchers crafted a consent form approved by a Nigerian committee, but most of the families streaming in from rural villages were illiterate. The doctors used local nurses to talk to the families. Yet neither the parents, the nurses nor any other witnesses signed the sheets, the company said.

Pfizer described the lapse as a procedural error but stressed in a written statement that "verbal consent was obtained."

Nonetheless, Hopkins and Dutse said that the nurses did not translate the full consent form.

"To be honest with you, it was a general explanation," Dutse said. "It is very complicated for them. You explain to them it's a new medicine and you have a right to say no."

In many instances, Dutse recalled, parents scanned the American faces and then begged him to make the decision. His reply: "That's the only thing to do."

"I take the responsibility at the end of the day," Dutse said. Given their poverty and lack of access to decent medical care, "Honestly, did they have a choice?"

Urondu said the researchers should have stressed that there was an alternative: Walk a few yards to a Doctors Without Borders tent.

Today, it is impossible to ask the Nigerian families how much they understood, Dutse said, because there is no way to locate "rural people with no address."

Lodi, the physician from Doctors Without Borders, said he believes they did not comprehend what was happening. He said he treated some of the children after Pfizer's researchers left. As he explained in an e-mail: "All those patients and their families came back saying that they had never been informed that they were used in experimentation with an unproved medicine."

Yola, the Kano physician, stressed that such questions about consent would never arise in America, where "they have everything to protect a patient from a doctor."

Side Effects

Many American doctors remain leery of giving quinolone antibiotics to children for fear they might develop arthritis. Some researchers have used joint specialists and sophisticated electronic equipment to search for damage during studies.

The Kano medical camp had neither specialists nor expensive equipment – even the hospital's X-ray machine was broken, Dutse said.

As they arrived, 60 children showed signs of joint pain, a common result of meningitis, according to the experiment's final report. Dutse worried that the pain could mask swelling or erosion caused by Trovan. "Honestly, I was very scared of that," Dutse said. "What if anything happened? I could not forgive myself."

Dutse inspected knees and ankles, hoping to discern any damage caused by Trovan. His final report concluded that the antibiotic harmed none of the children in this way. (The later Trovan experiment, which was only partially completed, also found no evidence of joint damage.)

Yet, Dutse said, "Did we miss some quinolone arthritis? It's possible."

Statistics accompanying the experiment's final report showed that seven children who took Trovan and seven who took the comparison drug had full-blown arthritis. Fifteen children who took Trovan showed signs of joint pain during the experiment, a rate three times that of children who took the comparison drug.

Hopkins called the statistics insignificant, and Pfizer said there is no data to suggest that Trovan is associated with joint pain. But Hopkins said the European Union later balked at marketing Trovan to children – in part due to the Nigerian joint pain figures.

Aftermath in Kano

Pfizer's researchers departed Kano after treating victims for about two weeks, leaving each child with a list of medications taken. Any child who remained ill was transferred across town to a better-equipped hospital, the company said.

But Lodi contends that Doctors Without Borders assumed care of some of the children and saw no medical records. The physicians could only guess how to continue treatment, he said.

Researchers asked the children to return in four to six weeks to ensure they remained healthy and free of side-effects. Less than half showed up, Dutse said.

Although U.S. medical guidelines governing meningitis experiments recommend long-term follow-ups, Pfizer's experiment called for no additional checks. The company said medical literature supported a six-week follow-up period for the type of meningitis in Kano and that it saw no unusual side effects among the children who did return.

The experiment's final report concluded that Trovan and the comparison drug were equally safe and effective. It also disclosed that 45 children received treatment deviating from the experiment's preapproved plan.

Pfizer said the errors did not compromise patient care.

Despite the problems, Dutse said he believes children benefited from Pfizer's visit. But he also voiced concerns. If a corporate giant landed in Kano again, Dutse said, he would want solid guarantees of continuing assistance from the company.

"In the future, we will have clear terms," Dutse said. "These things have opened our eyes... You are dealing with human beings, whether they are American children or they are Nigerian children. They are entitled to the best."

Fallout and Failure

By December 1996, Pfizer had tested oral and intravenous Trovan on 13,000 people in 27 countries. Late that month, the company applied to the FDA for approval to market Trovan.

Six months later, FDA inspectors traveled to Pfizer's Groton, Conn., research campus to examine documents from Nigeria. Sorting through raw results recorded in Kano, inspectors discovered nearly four dozen discrepancies.

One document listed a child's white blood cell count as 68; another pegged it at 680. Other records showed that some lab tests had been conducted in Kano when they actually were done in Connecticut, the FDA said, and Pfizer could not recall who recorded some of the data.

Pfizer said any discrepancies noted by FDA "did not compromise the validity of the trial or its conclusions."

The FDA would not discuss why it never approved marketing Trovan for children – such specifics are considered corporate secrets. But Pfizer said that it withdrew its request to use the drug against "epidemic meningitis" after regulators indicated they would deny it based on a range of concerns – including the failure to conduct adequate follow-up exams.

Nonetheless, the FDA authorized marketing Trovan for use against 14 adult illnesses on Dec. 19, 1997. Later, the European Union approved Trovan but specifically advised that "Trovan tablets . . . should not be given to children."

Pfizer sponsored a February 1998 launch meeting in Orlando. More than 1,800 sales people rhythmically chanted "Tro-van, Tro-van, Tro-van," a company magazine recounted. The company emblazoned its annual report with a photo of Hopkins and other Trovan team members.

The drug quickly became one of the most prescribed antibiotic brands in the United States. Pfizer reported that sales topped \$160 million in Trovan's first year and roughly 2.5 million adults had taken it by mid-1999.

But just as suddenly, regulators announced bad news. During 16 months on the market, there had been 140 reports of liver problems in Trovan patients. At least 14 suffered liver failure and six died.

Pfizer said no serious liver problems had surfaced in its experiments, including the Nigeria tests.

U.S. regulators advised doctors to restrict Trovan use to patients with serious diseases whose need was great enough to outweigh the risks of liver damage. European regulators suspended Trovan sales altogether.

In the aftermath, at least 16 patients and family members have filed lawsuits claiming liver injuries and one death. Pfizer aborted an international pediatric meningitis experiment and told stockholders it had suffered "a disappointment" with Trovan.

Since then, Pfizer has acquired Warner-Lambert Co. to become the largest drug maker in the world. Hopkins left Pfizer to become an independent consultant. Dutse ascended to dean of the Kano medical school. Lodi now works with refugees in Guinea. No one is quite sure what became of the rural children in the experiment.

And, as of last fall, Urondu remained at the Kano Infectious Disease Hospital, working 70-hour weeks among the cholera victims laid low by the latest epidemic to sweep across the arid plains of northern Nigeria.

"I love this job; I work every day," Urondu explained recently while on rounds. "They see you," he said of his emaciated patients, and "after God, you are the next person."

And as for Pfizer? Urondu smiled without humor.

"They left before the party was over," he said.

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